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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,958	01/16/2004	Detlev Suckau	B0004/7117	6208
64967 7590 10/01/2007 LAW OFFICES OF PAUL E. KUDIRKA 40 BROAD STREET SUITE 300 BOSTON, MA 02109			EXAMINER GAKH, YELENA G	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/758,958	Applicant(s) SUCKAU ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/17/04, 09/17/04, 05/05/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 3 is objected to because of the following informalities: the claim obviously contains a typo - it recites "time" instead of "space" "mass spectrometer". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method comprising the steps (c) and (d) of claim 5, does not reasonably provide enablement for the method, which omits such steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not enable any person of ordinary skill in the art to perform the method recited in claims 1-4 and 13-15, which does not comprise the steps of spontaneous fragmentation of the biomolecule with forming different type of ISD ions followed by acceleration of the ions for their injection in the first mass spectrometer of a tandem mass spectrometer and selecting specific species utilizing this first spectrometer.

Claims 5-7 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method comprising a step of collision fragmentation of ISD ions, such as CID, SID, PID collision or LID decay, in step (e), does not reasonably provide enablement for the method, which omits such step. The specification discloses further fragmentation of ISD ions to form granddaughter ions specifically by such collision methods without providing any guidance for other ways of fragmentation of ISD ions.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites in its preamble that the biomolecule is ionized by means of MALDI spectrometry; however, no MALDI conditions are recited in the body of the claim (e.g. mixing the biomolecule with MALDI matrix), which makes it unclear, as to how specifically MALDI is involved in the process. Moreover, since it is well known that MALDI can be performed in different ways depending on adding analyte to the matrix, which affects performance of mass spectrometric analysis, omitting important steps related to utilizing MALDI in the body of claims 1-4 renders them unclear and indefinite.

Further, it appears that claim 1 and dependent claims omit essential steps for performing the method, such as those recited in claim 5, which additionally renders them unclear and indefinite. It is not apparent, as to how the method recited in claim 1 can be performed without e.g. step (d) recited in claim 5.

It is not clear from claims 1-8, how the species of ISD fragments are selected for further fragmentation.

Claim 10 is not clear in regards to utilizing different matrix substances for performing the method. Does the claim recite repeating all steps of claim 9 each time for a different matrix substance, or it means using different matrix substances as a mixture for a single analysis?

Claim 13 omits essential steps for performing the method, such as obtaining the granddaughter spectra before comparing them, and, in particular obtaining the ion series in the specific manner recited in the claim. Claims 13-15 are unclear and indefinite as lacking specific steps required for performing the method recited in the claims.

Claim 14 is unclear regarding the recited computer program - is this a commercially available computer program, or it is a part of the invention? If the program is a part of the invention, the algorithm of the program should be a part of the claimed method in order for the method to be enabled. Clarification is requested.

Allowable Subject Matter

4. **Claim 8** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the method recited in claim 8, which however remains unclear and indefinite regarding the step of selecting one species of ISD fragment ion in the first mass spectrometer.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Brown et al. (Anal. Chem., 1995)* teach "sequence-specific fragmentation of matrix-assisted laser-desorbed protein/peptide ions" (Title); *Takayama et al. (Int. J. Mass Spectrom., 1998)* study, "does in-source decay occur independent of the ionization process in matrix-assisted laser desorption?" (Title); *Suckau et al. (Anal. Chem., 2003)* teach "T³-sequencing: targeted characterization of the N- and C-termini of undigested proteins by mass spectrometry" (Title); *Suckau et al. (Anal. Bioanal. Chem., 2003)* teach "a novel MALDI LIFT-TOF/TOF mass spectrometer for proteomics" (Title); *Liu et al. (J. Am. Soc. Mass Spectrom., 2005)* teach "optimization of a MALDI TIOF-TOF mass spectrometer for intact protein analysis" (Title); *Köcher et al. (Anal. Chem., 2005)* teach "fragmentation of peptides in MALDI in-source decay mediated by hydrogen radicals" (Title); *Wuhrer et al. (Rapid Commun. Mass Spectrom., 2006)* teach "matrix-assisted laser desorption/ionization in-source decay combined with tandem time-of-flight mass spectrometry of permethylated oligosaccharides: targeted characterization of specific parts of the glycan structure" (Title); *Toyoda et al. (Review Sci. Instrum., 2007)* teach "high-energy collision induces dissociation fragmentation pathways of peptides, probed using multistage tandem time-of-flight mass spectrometer "MULTI-TOF/TOF".


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/26/2007


YELENA GAKH
PRIMARY EXAMINER